
NEWS RELEASE

Judd Gregg

United States Senator for New Hampshire
393 Russell Building, Washington, D.C. 202-224-3324 www.senate.gov/~gregg/



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Contact: Erin Rath/Jeff Turcotte

BREAKTHROUGH, BIPARTISAN LEGISLATION TO MAKE MORE PRESCRIPTION DRUGS AFFORDABLE, AVAILABLE GETS BOOST

Legislation is approved by Senate HELP Committee, under Sen. Gregg's leadership

WASHINGTON— People will soon have more prescription drugs available at lower cost thanks to a bipartisan plan that was approved today by the Senate Health, Education, Labor and Pensions Committee announced U.S. Senator Judd Gregg, Chairman of the Senate HELP Committee. Passage of this legislation marks the end of more than five years of negotiations and discussions over the issue of generic drugs. The bill is now ready for consideration by the full Senate.

“The bill we are passing through committee today marks the end of five long years of partisan gridlock and represents a victory for every person in America who has ever used a prescription drug to enhance or prolong their life and good health. The Greater Access to Affordable Pharmaceuticals (GAAP) Act will would eliminate the various practices some brand-name pharmaceutical and generic companies have used to delay consumers access to low-cost affordable medicines. It also does it in a way that protects innovation and preserves the incentive for companies to invest in the research & development of the next generation of newer, better, and safer drugs,” Gregg said. “It is the right thing to do and the right way to do it. I’m extremely pleased that we have been able to put politics aside and put the American people first.”

The agreement reached by Senators Judd Gregg, Charles Schumer (D-NY), John McCain (R-AZ) and HELP Ranking Member Ted Kennedy (D-MA) will enable less expensive generic drugs to be sold in pharmacies. The Gregg-Schumer proposal overhauls provisions of Hatch-Waxman (drug patent laws) that have created a significant stifling of the system with frivolous law suits, which delay life-saving drugs from reaching consumers in efficient and less expensive means. The plan also strengthens a Food and Drug Administration proposal from last fall that was intended to pave the way for generics to come to the market faster and shield that proposal from legal challenges.

A summary sheet of the key elements of the Greater Access to Affordable Pharmaceuticals Act, the Gregg-Schumer proposal, is attached.

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KEY ELEMENTS OF THE BIPARTISAN GENERIC DRUG PLAN

1) **One 30 Month Stay** - The name-brand company would get a single 30 month stay. The stay would be triggered if a name-brand company sues a generic application for infringing on any patent on a blockbuster drug that is filed before a generic application is submitted to the FDA.

Once a generic application is filed, the name-brand company has 45 days to challenge the generic application in court. If the name-brand does not challenge the generic company's application within 45 days, the generic can seek a declaratory judgement indicating that it does not violate the name-brand drug's patents.

The single 30 month stay would run concurrent to the FDA's consideration of the generic company's application. As such, the 30 month stay would not be likely to cause significant delay in the generic's introduction to the marketplace. (It usually takes the FDA 18 to 25 months to approve a generic drug.) In contrast, the FDA's proposed rule would allow the stay to be triggered up to the eve of the generic drug coming to market.

2) **Enforcement** - The Gregg-Schumer plan does not specify which patents can be listed in the FDA's Orange Book. To ensure that the name-brand companies do not use frivolous patents to keep generic drugs off the market, the proposal would create a new enforcement mechanism.

Gregg-Schumer would allow generic companies to file counter-claims if a name-brand company sues them for violating a patent. For example, if a name-brand files a frivolous patent and sues a generic applicant for violating that patent in order to trigger the 30 month stay, the generic company can counter-sue the name-brand and argue that the patent should never have been listed in the Orange Book in the first place.

3) **180 Day Exclusivity** - Currently, the first generic drug company who is able to come to market gets 180 days of exclusivity. Gregg-Schumer sets up "forfeiture provisions" similar to those in earlier generic drug legislation which prevent the generic companies from abusing this incentive.

Under the bill, a generic drug company would forfeit its rights to this exclusivity if it was found to have made an anti-competitive deal with a brand company or otherwise fails to come to market in a timely manner. If one of the forfeiture provisions outlined in the bill occurs, the exclusivity would be forfeited and the marketplace would open up to any generic company ready to come to market.

4) **Bioequivalence** - Under the current statute, the primary method by which the FDA determines whether a generic is equivalent to a brand drug ("bioequivalence") is by measuring the rate and absorption of the drug into the bloodstream. For certain drugs which are not absorbed into the bloodstream, such as topicals and inhalers, the FDA uses different tests to determine bioequivalence, which are defined in their regulations.

Brand companies have challenged FDA's use of these regulations, which has led to delay in the approval of generic versions of these drugs. Gregg-Schumer would clarify that the FDA does have the authority to establish separate tests for determining the bioequivalence of drugs which are not absorbed into the bloodstream - as long as those tests are scientifically valid and meet rigorous standards.